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10/672,069	09/25/2003	Tariq M. Rana	UMY-062	4721

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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,069	RANA, TARIQ M.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-39 and 67-68, drawn to a siRNA compound targeted to an mRNA sequence, classifiable in class 536, subclass 24.5.

II. Claims 40-63, drawn to a method of activating target-specific RNA interference in a cell or organism and a method of treating a disease or disorder by administration of a siRNA, classifiable in class 514, subclass 44.

III. Claim 64, drawn to a method of deriving information about the function of a gene in a cell or organism, classifiable in class 435, subclass 6.

IV. Claim 65, drawn to a method of validating a candidate protein as a suitable target for drug discovery, classifiable in class 435, subclass 6.

V. Claim 66, drawn to a kit comprising reagents for activating target-specific RNA interference in a cell or organism, classifiable in class 435, subclass 6.

VI. Claims 70(a) and 70(b,) drawn to a siRNA derivative comprising a crosslink or a psoralen crosslink, classifiable in class 536, subclass 24.5.

VII. Claims 70(c) and 70(d), drawn to a siRNA derivative comprising a biotin or photocleavable biotin, classifiable in class 536, subclass 24.5.

VIII. Claims 70(e) and 70(g), drawn to a siRNA derivative comprising a peptide or a Tat peptide, classifiable in class 536, subclass 24.5.

IX. Claims 70(f), drawn to a siRNA derivative comprising a nanoparticle, classifiable in class 536, subclass 24.5.

X. Claims 70(f), drawn to a siRNA derivative comprising a peptidomimetic, classifiable in class 536, subclass 24.5.

XI. Claims 70(f), drawn to a siRNA derivative comprising a dendrimer, classifiable in class 536, subclass 24.5.

XII. Claims 72 (a)(b)(c), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative contains a crosslink or a psoralen crosslink, classifiable in class 514, subclass 44.

XIII. Claims 72 (d), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative is modified at the 3' terminus, classifiable in class 514, subclass 44.

XIV. Claims 72 (e)(f), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA comprises a biotin or a photocleavable biotin, classifiable in class 514, subclass 44.

XV. Claims 72 (g), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative comprises a nanoparticle, classifiable in class 514, subclass 44.

XVI. Claims 72 (g), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative comprises a peptidomimetic, classifiable in class 514, subclass 44.

XVII. Claims 72 (g), 73-77, drawn to a method of contacting a concentration of an siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative comprises a dendrimer, classifiable in class 514, subclass 44.

XVIII. Claims 72 (g)(h), 73-78, drawn to a method of contacting a concentration of a siRNA derivative to inhibit expression of a target gene wherein the siRNA derivative comprises a peptide or a Tat peptide, classifiable in class 514, subclass 44.

XIX. Claim 79, drawn to a photocleavable biotin, classifiable in class 548, subclass 303.7.

XX. Claim 80-83, drawn to a method of determining whether a candidate siRNA derivative is a siRNA derivative, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I and group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product siRNA compound of group I can be used as a probe in *in situ* hybridization, which is materially different than the methods of

inhibiting activating target-specific RNA interference in a cell or organism of group II. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNAcompound of group I is a compound inhibitor, which is materially different than a method for deriving information about the function of a gene which involves determining the characteristic of a cell or organism, as present in group III. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNA compound of group I is used as an inhibitor of mRNA expression, which is materially different than a method for validating a candidate protein as a suitable target for drug discovery which

involves contacting the cell or organism with a siRNA compound and determining the function of a candidate protein in a cell or organism, as present in group IV. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNA compound of group I is a compound inhibitor capable of activating target-specific RNA interference which is materially different than used in a kit comprising reagents for activating target-specific RNA interference and which requires elements not necessarily found in a compound designed for inhibition. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and groups VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group I is drawn to a siRNA and the invention of groups VI-XI are drawn to siRNA derivatives,

which are not disclosed as useful together and have different structures. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and groups XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group I is drawn to a siRNA and the invention of groups XII-XVIII are drawn to a method of contacting a cell with a concentration of a siRNA derivative to inhibit expression of a target gene, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNA compound of group I and the photocleavable biotin of group XIX are structurally and functionally unrelated because the siRNA functions as a compound inhibitor and the

photocleavable biotin functions to pull out biotinylated siRNA molecules from cells using streptavidin. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group I and group XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNA compound of group I is a compound inhibitor, which is not used in the method of determining whether a candidate siRNA derivative is an siRNA derivative of group XX, which involves determining the expression of a siRNA derivative in a cell. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of activating target-specific RNA interference in a cell or organism by administration of a

compound inhibitor of group II is materially different than the method of determining the function of a gene in a cell or organism, as present in group III, which involves determining the characteristic and property of a gene function in a cell or organism. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of activating target-specific RNA interference in a cell or organism by administration of a compound inhibitor of group II is materially different than the method of validating a candidate protein as a suitable target for drug discovery, as present in group IV, which involves determining the characteristic and property of a protein function in a cell or organism. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have

materially different modes of operation with different effects. For example, the method of activating target-specific RNA interference in a cell or organism by administration of a compound inhibitor of group II, is materially different than a kit comprising reagents for activating target-specific RNA interference in a cell or organism as present in group V which requires elements not necessarily found in the method of activating target-specific RNA interference. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and groups VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group II is drawn to a method of activating target-specific RNA interference in a cell or organism by administration of a compound inhibitor and the invention of groups VI-IX are drawn to siRNA derivatives, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and groups XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group II is drawn to a method of activating target-specific RNA interference in a cell or organism by administration of a compound inhibitor and the invention of groups XII-XVIII are drawn to a method of contacting a cell with a concentration of a siRNA derivative to inhibit expression of a target gene, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of activating target-specific RNA interference in a cell or organism by administration of a compound inhibitor of group II involves a compound inhibitor, which is structurally and functionally unrelated to a photocleavable biotin of group XIX. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group II and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of activating target-specific RNA interference in a cell or organism involves administration of a compound inhibitor of group II, which is not involved in the method of determining whether a candidate siRNA derivative is a siRNA derivative, which involves determining the expression of a reporter gene in a cell after administration of a siRNA derivative. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of deriving information about the function of a gene in a cell or organism of group III, involves determining the characteristic properties of a gene function in a cell or organism and is materially different than the method of validating a candidate protein as a suitable target for drug discovery as present in group IV, which involves determining the characteristic properties of protein function in a cell or organism. Furthermore restriction is proper because the subject

matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of deriving information about the function of a gene in a cell or organism of group III is materially different than a kit comprising reagents for activating target-specific RNA interference in a cell or organism, as present in group V, which requires elements not necessarily found in the method of deriving information about the function of a gene. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and groups VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group III is drawn to a method of deriving information about the function of a gene and the invention of groups VI-XI are drawn to siRNA derivatives, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-

coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and groups XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group III is drawn to a method of deriving information about the function of a gene and the invention of groups XII-XVIII are drawn to a method of contacting a cell with a concentration of a siRNA derivative to inhibit expression of a target gene, which are not disclosed as useful together and have different functions and modes of operation. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of deriving information about the function of a gene in a cell or organism of group III does not involve the use of a photocleavable biotin, as present in group XIX. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would

not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group III and group XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of deriving information about the function of a gene in a cell or organism of group III involves determining the characteristic properties of a gene function in a cell or organism and does not involve the method of determining whether a candidate siRNA derivative is a siRNA derivative, as present in group XX, which involves determining the expression of a reporter gene in a cell after administration of a siRNA derivative. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of validating a candidate protein as a suitable target for drug discovery of group IV involves determining the characteristic properties of proteins in cells and is materially different than a kit

comprising reagents for activating target-specific RNA interference in a cell or organism, as present in group V, which requires elements not necessarily found in the method of validating a candidate protein as a suitable target for drug discovery. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and groups VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group I is drawn to a method of validating a candidate protein as a suitable target for drug discovery and the invention of groups VI-XI are drawn to siRNA derivatives, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and groups XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group I is drawn to a method of validating a candidate protein as a suitable target for drug

discovery and the invention of groups XII-XVIII are drawn to a method of contacting a cell with a concentration of a siRNA derivative to inhibit expression of a target gene, which are not disclosed as useful together and have different functions and different effects. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of validating a candidate protein as a suitable target for drug discovery of group IV involves determining the characteristic properties of proteins in cells and does not involve the use of a photocleavable biotin, as present in group XIX. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group IV and group XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the method of

validating a candidate protein as a suitable target for drug discovery of group IV, which involves determining the characteristic properties of proteins in cells and is materially different than the method of determining whether a candidate siRNA derivative is a siRNA derivative, as present in group XX, which involves determining the expression of a siRNA derivative in a cell. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and groups VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the invention of group V is drawn to a kit comprising reagents for activating target-specific RNA interference in a cell or organism and the invention of groups VI-XI are drawn to siRNA derivatives, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and groups XII-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have

materially different modes of operation with different effects. For example, the invention of group V is drawn to a kit comprising reagents for activating target-specific RNA interference in a cell or organism and the invention of groups XII-XVIII are drawn to a method of contacting a cell with a concentration of a siRNA derivative to inhibit expression of a target gene, which are not disclosed as useful together and further the kit requires elements not necessarily found in the methods of groups XII-XVIII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and group XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the photocleavable biotin of group XIX is not used in the kit comprising reagents for activating target-specific RNA interference in a cell or organism of group V. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group V and group XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have

materially different modes of operation with different effects. For example, the kit comprising reagents for activating target-specific RNA interference in a cell or organism of group V, which involves elements and reagents that are not necessarily involved in the method of determining whether a candidate siRNA derivative is a siRNA derivative, as present in group XX, which involves determining the expression of a reporter gene in a cell after administration of a siRNA derivative. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the siRNA derivatives of groups VI-XI comprise a single crosslink, a psoralen crosslink, a biotin, a peptide or a nanoparticle all of which have different structures and different modes of operation and further are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups VI-XI and groups XII-XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of inhibiting expression of a target gene, as present in groups XII-XVIII, can be practiced with another materially different product, such as a ribozyme. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group VI-XI and groups XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the inventions of groups VI-IX are drawn to siRNA derivatives and the invention of group XIX is drawn to a photocleavable biotin which are entirely different molecules with different functions. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups VI-IX and groups XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the siRNA derivative of groups VI-IX can be used to affinity purify proteins used in RNA interference. Furthermore restriction is proper

because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group XII-XVIII and groups XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the inventions of groups XII-XVIII are drawn to a method of using a siRNA derivative to inhibit a target gene and the invention of group XIX is drawn to a photocleavable biotin, which are not disclosed as useful together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group XII-XVIII and groups XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the inventions of groups XII-XVIII are drawn to a method of using a siRNA derivative to inhibit a target gene and the invention of group XIX is drawn to a method of determining whether a candidate siRNA derivative is a siRNA derivative, which are not disclosed as useful together and further the

methods of determining whether a candidate siRNA derivative is a candidate siRNA derivative requires elements and steps not necessarily involved in the methods of inhibiting the expression of a target gene. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group XIX and group XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as useful together because they have materially different modes of operation with different effects. For example, the photocleavable biotin of group XIX is not disclosed as useful in the method of determining whether a candidate siRNA derivative is a siRNA derivative. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 69 link(s) inventions VI-XI and claim 71 link inventions XI-XVIII The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s),

claim 69 and 71. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to

final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Kimberly Chong
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